REMARKS

The Pending Claims

Claims 21, 60, and 70-85 are pending, which claims are directed to a polypeptide that comprises a particular amino acid sequence and binds with HIV gp120 under physiological conditions (claims 21, 70-77), and a composition comprising the polypeptide and a carrier (claims 60, 78-85).

Amendments to the Claims

The claims have been amended to point out more particularly and claim more distinctly the invention. Specifically, the phrase "or substantially identical to" has been deleted from claim 21. This amendment is supported by the specification, for example, at p. 3, line 32 – p. 4, line7. Also, claim 21 has been amended to include the term "contiguous" such that the claim now recites a polypeptide that comprises "less than 100 *contiguous* amino acid residues that are identical to the amino acid sequence of the human CCR5 chemokine receptor." This amendment is supported by the specification, for example, at p. 4, lines 11-19. Unless otherwise noted, all page numbers are with reference to the replacement specification submitted with Applicant's prior Response to Office Action dated June 24, 2004. No new matter has been added by way of these amendments.

Summary of the Office Action

The Office Action objects to the application for failing to meet the requirements of 37 C.F.R. § 1.821 because it allegedly contains sequences that are not identified by a sequence identifier. The Office Action rejects claims 21, 60, and 70-85 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Office Action also rejects claims 21, 60, and 70-85 under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter and allegedly lacking written description support. The Office Action further rejects claims 21 and 71 under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. patent 6,448,375 (Samson et al.). The Office Action rejects claim 79 under 35 U.S.C. § 103(a) as allegedly unpatentable over the same reference. Applicant requests reconsideration of these rejections in view of the amended claims.

Discussion of the Section 1.821 Objection

The Office Action objects to the application under 37 C.F.R. § 1.821 because the application allegedly contains sequences that are not identified by a sequence identifier. The

Office Action does not refer to any particular place in the application where a sequence identifier is missing.

A substitute specification and marked-up version of the originally-filed specification were submitted as Exhibits A and B, respectively, to the Applicant's Response to Office Action dated June 24, 2004. The substitute specification provides a sequence identification number for every amino acid sequence recited therein. Accordingly, Applicant believes no further amendments to the specification are necessary.

Discussion of the Rejection under Section 112, Second Paragraph

The Office Action alleges that the pending claims are indefinite for recitation of the phrase "substantially identical to." Although the Applicant believes that the claims are clear and definite as read by one of ordinary skill in the art in the context of the application, the claims have been amended to remove the phrase "substantially identical to" in order to expedite the prosecution of the application. Accordingly, the rejection is moot and should be withdrawn.

Discussion of the Rejection under Section 112, First Paragraph (New Matter)

The Office Action rejects the pending claims as containing new matter because the specification allegedly does not support claims to a polypeptide that comprises "less than 100 amino acid residues that are identical to the amino acid sequence of the human CCR5 chemokine receptor." The Office Action acknowledges, however, that the specification *does* support claims to a polypeptide that comprises "less than 100 *contiguous* amino acid residues that are identical to the amino acid sequence of the human CCR5 chemokine receptor" (Office Action at p. 3).

Contrary to the Office Action's allegations, the specification and original claims of the application clearly support claims to a polypeptide that comprises "less than 100 amino acid residues that are identical to the amino acid sequence of the human CCR5 chemokine receptor." Such support is provided, for example, in originally filed claim 21, and at p. 10, lines 21-24 of the specification (p. 11, lines 28-31 of the original specification).

Nevertheless, in order to expedite prosecution, and because the amendment does not narrow the scope of the claims, Applicant has amended the claims to recite a polypeptide comprising "less than 100 *contiguous* amino acid residues that are identical to the amino acid sequence of the human CCR5 chemokine receptor" as suggested in the Office Action. Accordingly, the "new matter" rejection is moot and should be withdrawn.

Discussion of the Rejection under Section 112, First Paragraph (Written Description)

The Office Action alleges that the pending claims lack written description support insofar as they recite a polypeptide comprising one of the three recited amino acid sequences with "up to 6 conservative or neutral amino acid substitutions." The Office Action states three specific reasons in support of the rejection: (1) the application allegedly fails to disclose the isolation and purification of polypeptide variants of the claimed sequences having up to six conservative or neutral amino acid substitutions, (2) the application allegedly fails to set forth the molecular determinants modulating the properties of the polypeptides, and (3) single amino-acid substitutions can have unpredictable effects on peptide activity. Applicant respectfully traverses this rejection.

With regard to reason (1), above, there is no requirement that the applicant provide working examples of the claimed invention, much less provide working examples of each and every embodiment of an invention that falls within a claimed genus. Such a requirement would be unduly burdensome for the applicant, and is unnecessary in order to meet the written description requirement.

With regard to reason (2), above, contrary to the Office Action's allegation, the application *does* set forth the molecular determinants modulating the properties of the claimed genus of polypeptides. As is clear from the claims themselves, the members of the claimed genus share the common structural (e.g., molecular) motif of an amino acid sequence based upon one of three, explicitly described amino acid sequences: SEQ ID NOS: 12, 14, or 15. The fact that the genus encompasses such sequences comprising up to six conservative or neutral amino acid substitutions does not detract from this structural commonality of the genus. It is well within the skill of the ordinary artisan to predict and determine whether a given amino acid substitution is conservative or neutral, and the specification provides specific guidance on this point (e.g., specification at p. 7, line 12 – p. 8, line 11, and Example 6 at pp. 50-53). Furthermore, the specification describes the correlation between the structure and function of the claimed genus of polypeptides. For instance, Example 1 illustrates that SEQ ID NOS: 12, 14, and 15 bind with high affinity to HIV gp120 (e.g., in Example 1, SEQ ID NOS: 54 and 55 correspond (in part) to SEQ ID NO:12; SEQ ID NOS: 93 and 94 correspond (in part) to SEQ ID NO: 14; SEQ ID NO:105 corresponds to SEQ ID NO: 15). Example 1 further illustrates that amino acid sequences comprising only a portion of SEQ ID NOS: 12, 14, and 15 also bind to HIV grp120 with relatively high affinity (e.g., in Example 1, SEQ ID NOS: 53 and 56 contain part of SEQ ID NO: 12; SEQ ID NOS: 92-95 contain part of SEQ ID NO: 14; SEQ ID NOS: 102-104 contain part of SEQ ID NO: 15), but that other amino acid sequences that comprise a different portion of SEQ ID NOS: 12, 14, or 15 do not

share the same binding affinity with HIV grp120 (e.g., in Example 1, SEQ ID NOS: 50-52 and 57-59 contain part of SEQ ID NO: 12; SEQ ID NOS: 89-91 and 96-98 contain part of SEQ ID NO: 14; SEQ ID NOS: 101 and 106-109 contain part of SEQ ID NO: 15). Thus, contrary to the Office Action's allegations, the application more than adequately describes both the structural motifs of the claimed genus, and the correlation between function and structure, so as to show possession of the claimed subject matter in accordance with the written description requirement of Section 112.

With regard to reason (3), above, the degree of "predictability" as to whether a claimed invention will work is a matter typically related to enablement, not written description. Nevertheless, with regard to whether the effects of the amino acid substitutions are "predictable," Applicant notes that the claims are not directed to polypeptides comprising *any* substitution in the claimed sequences. Rather, the claims are limited to a small number of *conservative or neutral* substitutions. As mentioned above, it is well-within the skill of the ordinary artisan to predict and determine whether any given amino-acid substitution would be conservative or neutral, and the specification provides clear guidance on this point (e.g., specification at p. 7, line 12 – p. 8, line 11, and Example 6 at pp. 50-53). Accordingly, the subject matter of the pending claims meets the requirements of Section 112 in this regard.

For the foregoing reasons, the subject matter of the pending claims meets the written description requirement of Section 112, first paragraph. Accordingly, this rejection should be withdrawn.

Discussion of the Rejections under Section 102(e) and 103(a)

The Office Action rejects claims 21 and 71 as allegedly anticipated by U.S. patent 6,448,375 (Samson et al.) under 35 U.S.C. § 102(e). The Office Action also rejects claim 79 as allegedly obvious in view of the same reference under 35 U.S.C. § 103(a). In support of these rejections, the Office Action cites SEQ. ID. No.:11 of Samson et al. as allegedly disclosing a polypeptide that comprises a sequence recited in the present claims (e.g., SEQ ID NO: 13), and contains less than 100 contiguous amino acid residues that are identical to the amino acid sequence of the human CCR5 chemokine receptor, thereby allegedly meeting all of the elements of claims 21 and 71. The Office Action further alleges that it would have been obvious to combine the disclosed polypeptide with a carrier to provide a composition that meets all of the elements of claim 79. Applicant traverses these rejections.

Contrary to the Office Action's allegations, Samson et al. does not disclose any polypeptide comprising the amino acid sequence of SEQ ID NO: 11 that falls within the scope of the pending claims. To the contrary, SEQ ID NO: 11 is a partial sequence listing

that corresponds to the full-length human CCR5 polypeptide, which is outside of the scope of the pending claims. This fact is made clear at col. 14, lines 37-54 of Samson et al., which is the only passage of the cited reference that refers to SEQ ID NO: 11. In this passage, Samson et al. compares the amino acid sequence of a full-length, non-functional, "mutant" CCR5 polypeptide (ΔCCR5) with the amino acid sequence of a full-length, "normal" CCR5 polypeptide. In order to illustrate the differences between these polypeptides, the amino acid sequence of the region surrounding the mutation in ΔCCR5 was aligned with the corresponding region of the "normal" CCR5 polypeptide, and the alignment was depicted in Figure 6 of Samson et al. For the purposes of this illustration, the aligned sequences were provided with sequence identification numbers (SEQ ID NO: 11(normal) and SEQ ID NO: 13 (mutant)).

Thus, SEQ ID NO: 11, as disclosed in Samson et al., refers only to the full-length CCR5 polypeptide, which is outside of the scope of the pending claims. Samson et al. does not disclose any polypeptide other than the CCR5 polypeptide that comprises the amino acid sequence of SEQ ID NO:11, nor does Samson et al. in any other manner disclose a polypeptide that falls within the scope of the pending claims. Accordingly, Samson et al. does not anticipate the pending claims.

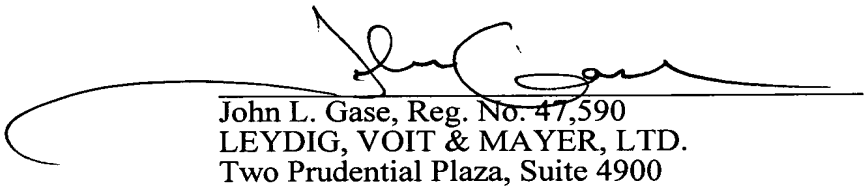
Furthermore, nothing in Samson et al. provides any motivation to modify the disclosures provided therein in such a way as to arrive at a polypeptide as defined by the pending claims. Samson et al. does not, for instance, suggest the desirability of selecting any of the particular sequences recited in the pending claims, and using such a sequence in a polypeptide as claimed. Accordingly, the disclosure of Samson et al. does not render obvious the subject matter of the pending claims.

For the foregoing reasons, the pending claims are patentable over Samson et al., and the anticipation and obviousness rejections should be withdrawn.

Conclusion

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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10/084,813 Application No.:_____

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: see R2 of office act.

May Need To
Applicant ~~Must~~ Provide:

☒ An ~~initial or~~ substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An ~~initial or~~ substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

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